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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,027

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Karim Ioualalen

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BLANK ROME LLP

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WASHINGTON, DC 20037

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

11/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,027	Applicant(s) IOUALALEN ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11 and 13-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 13, 14 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Amendments and Remarks filed, filed 7 August 2009, in the matter of Application N° 10/550,027. Said filings are entered on the record. The Examiner further acknowledges the following:

No claims have been added or amended.

Claims 6 and 12 are newly cancelled.

No new matter has been added.

Thus, claims 1-5, 7-11, 13, 14 and 21-27 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

WITHDRAWN OBJECTIONS

Objection to the Abstract

Applicants have submitted a substitute Abstract which complies with 37 CFR 1.52(b)(4). Thus, the objection now stands **withdrawn**.

Objection to the Claims

The objection to claim 6 set forth in the previous rejection is rendered **moot** in view of Applicants' cancellation of the claim.

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MAINTAINED OBJECTIONS/REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 7 May 2008 since the art which was previously cited continues to read on and render obvious the presented limitations.

CLAIM REJECTIONS - 35 USC § 103

(PREVIOUSLY MAINTAINED)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blichare et al. (USPN 4,132,753) in combination with Lantz et al. (USPN 3,146,167).

The instant claims are directed to a system comprising spherical, hydrophobic particles wherein said particles comprise at least one hydrophobic wax, and at least one non-neutralized fatty acid. With regard to the limitation, wherein the system is solid at a temperature of up to

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45°C, as recited in claim 2, until some material difference in the properties of the claimed composition are demonstrated distinguishing it from the art, said limitation is considered by the Examiner to be directed toward the instantly claimed composition.

The teachings to Blichare et al. are discussed above [*and are reproduced here for Applicants' convenience*].

Blichare et al. teach production of spherical, controlled-release granules comprising the active and a finely-divided wax-like material (claims 1 and 13). Said wax-like material is taught as consisting of waxes such as white beeswax, castor wax and Carnuba wax (claim 2). The wax-like material is also taught as comprising non-neutralized fatty acids such as myristic and stearic acids (claim 2).

Blichare further teaches in claim 1, that the melting point of the wax-like material is between about 30°C and about 100°C. Melting point temperature ranges for some of the wax-like material components are also taught (col. 3, lines 12-26).

The teachings to Lantz are also discussed above [*and are reproduced here for Applicants' convenience*].

Lantz et al. teach an oral pharmaceutical preparation having sustained release properties comprising solid substantially spherical lipid pellets having a solid medicament (claim 3). The sustained release or "time-delay" release material is taught as comprising admixed waxes such as Carnuba wax, beeswax and mineral wax, and fatty acids, such as stearic, lauric or myristic acids (col. 3, lines 41-51 and lines 58-60).

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Lantz further advantageously teaches that the time-release or sustained release material will be solid at room temperature, but also has a low melting point of from 40°C to about 150°C (col. 3, lines 36-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a system of galenic (e.g. lipidic droplet) particles comprising at least one hydrophobic wax and at least one non-neutralized fatty acid, modify the proportions of the ingredients to attain the desired melting point temperature, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the inventions practiced by both Blichare et al. and Lantz et al. overlap in their teachings of solid, spherical-shaped, active-infused, pellet compositions whose release material is comprised of wax materials (e.g. Carnuba, bee and vegetable waxes) as well as overlapping fatty acids (e.g. stearic and myristic acids). Given the overlap in hydrophobic release materials, it then follows, absent any unexpected results that the materials also overlap in their respective melting points.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

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CLAIM REJECTIONS - 35 USC § 103

(NEWLY PRESENTED IN PREVIOUS REJECTION)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Ioulalen et al. (USPN 6,572,892) and Blichare et al. [*emphasis added to reflect claim change*].

The '692 patent is the English publication of WO 99/65448, which was published 23 December 1999, but only in French.

The amended independent claim 1 is directed to a "galenic" system comprising hydrophobic solid lipid particles comprising at least one hydrophobic wax, at least one non-neutralized fatty acid and an active constituent which has been "eliminated from the surface" of said lipid particles (claim 1). Claim further limits the particles such that they a.) have a particle size between 0.5 and 1,500 microns, b.) contain no water, surfactants, emulsifying agents or

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traces of solvents, and c.) have a melting point between 15°C and 75°C. The term “galenic” is interpreted as defined by Applicants’ instant disclosure as being synonymous with lipid-based particles (see pg. 7, lines 9-12). Regarding the phrase “eliminated from the surface”, the Examiner broadly and reasonably interprets the phrase as reciting a structural limitation whereby the active agent is not present at the surface of the composition. Claim 6 is interpreted as reciting the same subject matter as claim 1, as discussed above.

Ioulalen et al. teach a composition comprising a solid hydrophobic blend which contains no water, surface-active agents, or emulsifying agents, and which contains at least one hydrophobic wax, an oil and a cosmetic or pharmaceutical active principle (Abstract; claim 1). Said blend is taught as being a solid at room temperature and “in practice” the final blend is taught as having a melting temperature of 30°C (col. 4, lines 10-11). The final product is further taught as having a preferred bead-size ranging from 1 to 10,000 microns (Abstract). Ioulalen also teaches multiple techniques for producing said particles. However, none the methods expressly discuss the formation of a compound where the active constituent has been eliminated from the surface of the particle consists of dispersing the blend in a liquid which is not miscible (col. 4, line 66 to col. 5, line 5).

The teachings of claim 1 of Blichare expressly teach the formation of particles comprising a hydrophobic wax-like material and a powdered medicament, whereby the wax-like material is heated to a temperature which liquefies the wax-like material, but not the medicament. Once the wax-like material achieves a molten state, the powdered medicament “sinks” into the wax-like material (e.g. away from the surface of the particle). The particles are then cooled and the active captured inside the wax-like material.

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It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated the heating/cooling mixing method taught by Blichare into the method of Ioulalen in order to achieve the instantly claimed composition, particularly one which comprised no active constituent on the surface of the particles. The ordinarily skilled artisan would have been highly motivated to incorporate the method of Blichare particularly because both the inventions of Blichare and Ioulalen are drawn to producing hydrophobic wax-based microparticle compositions comprising an embedded active ingredient and because both practiced inventions employ methods which are highly similar, if not anticipatory of one another, for embedding said active within the hydrophobic carrier.

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Claims 2-5, 8-11, 13, 14, 21, 22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ioulalen et al. with respect to claim 1 as set forth above.

The amended independent claim 1 is directed to a “galenic” system comprising hydrophobic solid lipid particles, as discussed above.

Claim 2 is directed to a limitation whereby the composition of claim 1 is solid at a temperature of up to 45°C. Claim 13 recites the composition of claim 1 as having a melting temperature between 30°C and 45°C after incorporation of the active (i.e. the final blend). New

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claim 21 recites that the composition of claim 1 is solid at a temperature of up to 37.5°C. Said limitations are expressly taught (col. 3, lines 11-15), wherein the final blend has a melting temperature between 15°C and 70°C and more preferably between 20°C and 45°C. The final blend is preferably taught as having a melting temperature of 30°C (col. 4, lines 10-12).

Claim 3 recites that the particles of the composition of claim 1 have a spherical form. Said limitation is expressly taught in that the compounds obtained in the invention of Ioulalen are shaped to give spherical hydrophobic particles called pearls (col. 4, lines 17-18).

Claim 4 further limits the hydrophobic wax of claim 1 to one which is vegetable-, animal- or mineral-based. Claim 8 recites specific types of animal-, and mineral-based waxes, whereas claim 24 recites more specific forms of vegetable-based waxes. Claims 5 and 22 recite that the composition of claim 1 comprises a weight percentage of wax ranging between 0.5 wt% and 99 wt% and between 1 wt% and 55 wt%, respectively. Ioulalen expressly teaches that the preferred wax compounds include: Carnuba, Candelilla, Alfa, ozokerite, beeswax, and vegetable oils such as olive, rice, jojoba and absolute flower waxes (col. 3, 21-31). The composition is further taught as comprising from 0.1% to 40% of the aforementioned waxes (col. 3, lines 21-22) and more preferably, the percent weight of hydrophobic waxes in the blend ranges from about 1 wt% to about 40 wt% (col. 4, lines 9-11).

Claim 7 recites that the melting point of the wax recited in claim 1 is between 15°C and 75°C, whereas new claim 23 recites a wax melting point temperature ranging between 30°C and 45°C. Ioulalen expressly teaches the use of palm tree oil, a species of palm oil, which in addition to teaching the limitations of claim 8, is further expressly taught as being part of a blend having melting point between 0° and 45°C (col. 49-55).

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Claim 9 recites that the non-neutralized fat of claim 1 is comprised of fatty acids having linear chains ranging from 4-18 carbon atoms. Claim 25 further limits the fatty acids of claim 1 to myristic, lauric, palmitic or oleic acid. Claims 10 and 26 recite that the composition of claim 1 comprises a weight percentage of fatty acid ranging between 0.5 wt% and 75 wt% and between 1 wt% and 30 wt%, respectively. The above limitations are expressly taught in that the composition which is practiced by Ioulalen discusses using between 4% and 90% by weight of oily compounds such as sunflower oil. Sunflower oil is well known in the art as being composed of a variety of different fatty acids compounds including both palmitic and oleic fatty acids, as evidenced by Zimmerman et al. (*Journal of the American Oil Chemists' Society*; 1973).

Claim 11 further limits composition of claim such that the particle size is between 10 and 250 microns. Said limitation is expressly taught in the Abstract whereby particles of the practiced invention range from 1 to 10,000 microns.

Claims 14 and 27 recite that the composition of claim 13 wherein the capacity of the particles for holding the active ranges from between 0.02% and 75%, and 5% and 50%, by weight of the particles, respectively. The limitation recited by claims 14 and 17, which states "wherein the capacity of the particles for holding the active ranges from between..." is broadly and reasonably interpreted by the Examiner as reciting that "the particles comprise an amount of active agent ranging between...". The pearl formulations of the practiced invention are expressly taught as having a loading capacity for the active ingredient which ranges from 0.02% to 75% in relation to the pearl weight (col. 5, lines 55-57).

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It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have prepared the instantly claimed hydrophobic solid lipidic particles. The ordinarily skilled artisan, under the guidance of the invention practiced by Ioulalen et al., would have been highly motivated to produce the instantly claimed particles and would have had an equally high expectation of successfully doing so, particularly since the reference anticipates, if not, expressly suggests compositions which embodied by the instantly claimed limitations. Therefore, absent evidence to the contrary, the invention as a whole was *prima facie* obvious.

RESPONSE TO ARGUMENTS

Applicants' arguments with regards to the following have been fully considered but they are not persuasive:

- claims 1-3 under 35 USC 103(a) as being unpatentable over the combined teachings of Blichare et al. and Lantz et al.,
- claim 1 under 35 USC 103(a) as being unpatentable over the combined teachings of Blichare et al. and Ioulalen et al., and
- claims 2-5, 7-11, 13, 14, 21, 22 and 24-27 under 35 USC 103(a) as being unpatentable over the teachings of Ioulalen et al. with respect to claim 1 as set forth above (i.e. claim 1 over Blichare and Ioulalen).

Applicants attest that "the cited references fail to disclose 'an active constituent that has been eliminated from the surface of the lipidic particles'". Applicants further acknowledge the Examiner's interpretation of the teaching of Blichare at claim 1, wherein the hydrophobic wax

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carrier is heated such the medicament powder sinks into the molten surface (e.g. recedes from the surface) followed by cooling of the particle to fully encapsulate the active particle.

Applicants further allege that Blichare cannot be interpreted as disclosing that the active ingredient is eliminated from the surface particularly since the reference discloses the need for maintaining constant agitation during the mixing of the powder and wax-like material and that the degree to which the powder sinks into the wax is dependent upon the mixing parameters (e.g. agitation rate). Lastly, Applicants allege that the Examiner is relying on an argument of inherency, wherein the teachings of Blichare necessarily arrive at the instantly claimed composition

In response, the Examiner respectfully disagrees and submits that the invention of Blichare, as discussed above, expressly teaches that the active ingredient particles are applied to the molten surface of a wax-like carrier, an application which allows the powder to sink into the molten carrier itself. Admixture of the composition with a lubricant and cooling results in granules of a size ranging from 12-60 mesh.

In response to Applicants' argument that the reference(s) fail to show certain features of Applicants' invention, it is noted that the features upon which Applicants rely (i.e., mixing methods and parameters) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The fact that Blichare teaches or suggests a different method for achieving Applicants' composition does not change the fact that Applicants' composition is taught by the art.

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Regarding Applicants' remarks regarding the Examiner's "inherent" interpretation, it is respectfully pointed out that the Examiner is not taking the position that the art inherently embodies Applicants' instant invention. Rather the Examiner is setting forth a case of *prima facie* obviousness whereby the limitations of the Blichare reference (e.g. claim 1) expressly teach and suggest Applicants' instant limitations, namely that an active constituent which is encapsulated within a wax-like material and formed into granules. Regarding Applicants' limitation reciting that "an active constituent has been eliminated from the surface of the lipidic particles", it is the position of the Examiner that the Blichare reference expressly reads on this recitation, absent a clear showing of evidence to the contrary provided by Applicants. Furthermore, the Office does not have the facilities for examining and comparing the lipid-encapsulated particles of Applicants' composition with those taught by Blichare in order to establish that the prior art either does not possess the same material structural and functional characteristics of the claimed composition or even that it departs from the instantly claimed invention. In the absence of evidence to the contrary, the burden is upon the Applicants to prove that the claimed methods/products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Regarding the Lantz reference, Applicants allege that "because this reference fails to cure the deficiency of Blichare et al., their combination cannot render the present invention obvious". It is not immediately clear to what deficiency Applicants are referring. However, as discussed above, the Examiner is relying on the Lantz reference for its disclosure of sustained release

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properties attributed to the formation of medicated, spherically-shaped lipid pellets using the same waxes which are also taught as being used in the Blichare reference. Though Blichare does not explicitly discuss such properties, the Lantz reference does. Furthermore, since the claimed product and the product of the prior art substantially structurally and compositionally the same, it follows that a *prima facie* case of obviousness has been established (see MPEP §2112.01(I)).

Applicants rely on the same argument for Ioulalen as they do for Lantz regarding the inability for the reference to cure the deficiency of the other (e.g. Blichare reference). In the case of the Ioulalen, the Examiner presents that the Blichare reference teaches the “eliminated” limitation that the Ioulalen does not expressly teach.

Nevertheless, it appears that Applicants are arguing the Lantz and Ioulalen references individually, to which the Examiner respectfully reminds that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) [*emphasis added*].

For these reasons, Applicants’ arguments are found unpersuasive. Said rejection is therefore **maintained**.

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 21, 22, 24, 26 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 14, 15, and 19 of Ioulalen et al. (USPN 6,572,892). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending claims are directed to compositions which comprise solid lipid-based particles, both of which further comprise at least one hydrophobic wax or a blend of waxes, at least one fatty acid (e.g. plant oil; see claim 3 of '892), and at least one active constituent (see claim 15 of '892). The waxes recited by the instant claims 8 are also recited by claim 4 of the '892 patent. The instant claims 2 and 13 recite that the composition has a melting point ranging from 30°C -45°C, whereas claims 1 and 2 of the '892 patent respectively teach that the hydrophobic blend is solid at ambient (i.e. room temperature) and has a final melting temperature no greater than 70°C. The composition of the '892 patent is taught as being formed into sphere-shaped "pearls" (claim 7), which may range in size from 1-10,000 microns (claim 14). Lastly, claim 19 of the '892 patent teaches that the wax or wax-blend comprises 0.1% to 40% by weight of the composition. The key differences between the instant claims and the '892 patent are that the '892 patent does not expressly teach in its claims the melting point temperatures for the wax(es), the types of fatty acids and their

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weight percent ranges within the composition, or the specific types of vegetable oil recited by the instant claim 24.

RESPONSE TO ARGUMENTS

Applicants' response with regard to the rejection of claims 1-5, 7-11, 13, 21-24, 26 and 27 [*emphasis added to reflect cancelled claim 6*] on the grounds of nonstatutory obviousness-type double patenting over the patented teachings of Ioulalen et al. (USPN 6,572,892) have been fully considered but they are not persuasive.

Applicants allege that "[t]he Examiner fails to provide any reason why the present claims are obvious" over the '892 patent. Applicants further state that the Examiner fails to refer to his own obviousness rejection. Lastly, Applicants allege that the Examiner has not provided any analysis remotely in accordance with the MPEP. Thus, the claims are not obvious over the Ioulalen patent.

In response, the Examiner respectfully admits that since the Double Patenting rejection does physically follow the obviousness rejections involving Ioulalen in the rejection, that certain arguments directed at the obviousness of the '892 patent over the instant claims, may have at the time seemed redundant. However, the Examiner also respectfully submits that the double patenting rejection does expressly point out overlapping subject matter between both the instant and patented claims as well as key differences between said claim sets. It is thus the position of the Examiner that it would have been within the purview of the ordinarily skilled artisan to minimally arrive at an obvious variation of the instantly claimed composition, particularly in

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view of the guidance available at the time the instant invention was made, absent a showing of evidence to the contrary.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966.

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The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615